IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CYNTHIA B. EVANS,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

CIVIL ACTION NO. 3:04CV00097

MEMORANDUM OPINION

JUDGE NORMAN K. MOON

Pending before the Court are three motions in this products liability action of December 17, 2004: (1) the Defendant's May 16, 2005 Motion to Exclude Plaintiff's Designated Experts Douglas Townsend, Ph.D. and David Urquia, M.D.; (2) the Defendant's May 16, 2005 Motion for Summary Judgment; and (3) the Defendant's June 17, 2005 Motion to Strike Late-Filed Affidavits of Dr. David Urquia and Dr. W. Jeffrey Elias. This matter was referred to United States Magistrate Judge B. Waugh Crigler for proposed findings of fact, conclusions of law, and a recommended disposition. *See* 28 U.S.C. § 636(b)(1)(B). In his Report and Recommendation of August 23, 2005, the Magistrate recommended that the Court grant in part and deny in part the Defendant's motion for summary judgment; grant the Defendant's motion to strike the Plaintiff's late-filed affidavits for purposes of summary judgment consideration; and grant the Defendant's motion to exclude as to Dr. Townsend's product defect testimony, but deny this motion as to Dr.

Urquia. Both parties filed timely objections, on which oral arguments were heard on October 11, 2005. This matter is now ripe for determination.

Having reviewed the entire case and all relevant law, the Court shall reject the Magistrate's Report and Recommendation. The Court shall grant the Defendant's motion to exclude Dr. Townsend's testimony and grant the Defendant's motion for summary judgment. The remaining motions, the motion to exclude the two late-filed affidavits and the motion to exclude Dr. Urquia's testimony, go to issues of causation and medical necessity and are not necessary to the Court's determination that summary judgment be granted. Thus, the Court will not address them.

I. Facts

On December 17, 2004, the Plaintiff, Cynthia Evans, filed this products liability action against the Defendant, Medtronic, Inc.. This action concerns an allegedly defective component in the Medtronic Itrel 3 Spinal Cord Stimulation System, a device manufactured by the Defendant, which the Plaintiff had implanted in her on August 20, 2003. She alleges that a defect found in a component of this system during a later surgery necessitated the component's removal and its replacement with a slightly different component. She claims that the procedure during which this replacement component was implanted caused her to suffer serious injuries, including pain and quadriplegia.

The Medtronic Itrel 3 Spinal Cord Stimulation System

The Itrel 3 is an implanted prescription medical device used to alleviate chronic pain by sending electrical impulses to the spinal cord, blocking the transmission of pain signals to the brain. The device consists of three parts: (1) a thin polyurethane insulated wire lead, 13 inches

long and 0.05 inches in diameter, with imbedded stimulating electrodes at its tip; (2) a battery-powered electronic pulse generator; and (3) a lead extension line that connects the lead to the generator. The generator is implanted in the abdomen and is connected by means of a lead extension to the lead, which carries electrical impulses to electrodes implanted over the spinal cord.

Although the Itrel 3 can use multiple varieties of leads, two are relevant in this case: the Model 3487A "PISCES-Quad" percutaneous lead and the Model 3998 "Specify" lead (also knows as a "surgical" lead). The primary difference between the two is the size of their electrode tips, the tip of the percutaneous lead being the smaller of the two. The lead portion of the percutaneous lead consists of four thin, tightly coiled wires, covered by a polyurethane insulation. The electrode tip of the percutaneous lead is no bigger around than the lead itself and consists of tiny metal bands wrapped around the tightly coiled inner wire. The electrode of the percutaneous lead is implanted by threading it through the subcutaneous space adjacent to the spine to the area of the spinal cord where stimulation is needed.

The electrode tip of the surgical lead is imbedded in a flat, paddle shaped tip, which is larger than the wire portion of the lead. Due to the larger size of the surgical lead tip, its implantation requires a laminectomy, a procedure where a portion of the target vertebrae is removed to allow the electrode tip's insertion. Implantation of the percutaneous lead does not require such a procedure.

The lead is connected to the lead extension by a "connector" at the tip of the lead extension. The tail of the lead is inserted into the connector, which is then tightened over the lead by the manual tightening of four screws built into the connector. A silicone protective boot

covers this connection.

The Plaintiff's Pre-operational Medical History and Initial Surgeries

The Plaintiff's history with the Defendant's device is as follows. In February, 1998 she suffered an employment related back injury while lifting boxes, disabling her from work and causing her chronic bilateral arm pain. After other treatment options failed to reduce her pain, she decided to have the Itrel 3 implanted in her on the advice of Dr. Jeffery Elias, M.D., a neurosurgeon at the University of Virginia Medical Center. Dr. Elias implanted the device in her over the course of two surgeries, on August 20 and 27, 2003. On August 20, 2003, Dr. Elias implanted a percutaneous lead, making a cervical incision at the C-7 level of the Plaintiff's spine and threading the lead up towards her head to the C-2 level. The cervical vertebrae are located at the top of the human spine. He then inserted the tail end of the lead into a temporary connector, covered the connector with the protective boot, and sutured the boot into place. Finally, Dr. Elias anchored the lead to the cervical fascia, a layer of connective tissue located over the muscle in the spine, and closed the wound.

The purpose of the August 27, 2003 surgery was to complete the implantation of the Itrel 3 by implanting a permanent lead connector as well as the lead extension and impulse generator. After the surgery, the Plaintiff reported about a fifty percent reduction in pain.

The Plaintiff later developed an infection in the tissue surrounding the generator implantation site, and on September 24, 2003, Dr. Elias operated anew and removed the generator and part of the lead extension.[1] Dr. Elias did this by making an incision over the lead

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[1]The Plaintiff does not allege that this infection was the result of any defect in the Defendant's product.

extension and then cutting the lead extension just below the connector. He then made an incision over the generator, removing it and the portion of the lead extension connected to it. The lead and connector were left in place.

The November 12, 2003 Surgery

In November, 2003, Dr. Elias noted drainage near the area of the connector and decided to revise the implanted system so that the wound could heal properly. Thus, Dr. Elias operated again on November 12, 2003 in order to implant a new generator at a different site in the Plaintiff's abdomen and to redirect the tail of the lead there. This was to be done by first disconnecting the tail end of the lead from the connector at the flank incision[2] and then, from the cervical incision, pulling the lead out of its track on the right side of the Plaintiff's body and redirecting it through a new track on the left side.

Present at the November 12, 2003 surgery were Dr. Elias; Dr. Adam S. Kanter, M.D., a resident neurosurgeon; Dr. Robin J. Hamill-Ruth, an anesthesiologist; and John Fisher and Mark Thompson, two of the Defendant's sales representatives. Fisher and Thompson had no active involvement in the surgery and were present only for observational purposes and to explain to the Plaintiff after surgery how to work the device. After the cervical incision by which the Dr. Elias originally implanted the lead was reopened,[3] Dr. Elias left the room momentarily. During that time, Dr. Kanter began tugging on the exposed portion of the lead in order to remove it from its current track and redirect it to the other side of the Plaintiff's body. Fisher and Thompson differ

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[2]The flank incision was made in the Plaintiff's lower back at the area where the tail end of the lead met the lead extension and connector.

[3]The deposition testimonies of Dr. Elias, Dr. Kanter, Fisher, and Thompson provide conflicting accounts as to whether Dr. Elias or Dr. Kanter opened the cervical incision.

slightly in their accounts of Dr. Kanter's tugging.[4] Thompson testified that Dr. Kanter started trying to pull the lead extension connection up out of the flank incision by pulling the lead towards the Plaintiff's head with forceps. Thompson recalled that the lead would not come out and appeared to be stuck. Fisher, however, recalled Dr. Kanter tugging the lead with one hand in the cervical area, although he did not remember whether Dr. Kanter pulled the lead towards or away from the Plaintiff's head. Fisher described Kanter as tugging the lead with one hand in a repetitive pull and release fashion for 10-15 seconds. Fisher recalled making a comment to Thompson about the danger to the integrity of the lead posed by Dr. Kanter's tugging. He based this comment upon his experience with leads that had been damaged in the past by tugging or being pulled tight.

When Dr. Kanter's tugging produced no effect, Thompson left the room to find Dr. Elias. Dr. Elias returned to the operating room and prepared to disconnect the lead from the connector. He pulled the protective boot back from the tail end of the lead and noticed that the insulation cover on the lead had been fractured, the coils stretched, and one of the wires broken. He described that the opening in the insulation was akin to a split, open down to the wire, and that the insulation did not appear to have been cut, torn back, or peeled back. Dr. Elias recalled that the lead insulation was fractured just above the connector and probably would have been covered by the protective boot. Thompson, however, recalled that it had been damaged where the pulling occurred. Dr. Elias determined that the lead was unsalvageable and removed it. He then handed the damaged lead to the scrub nurse for disposal. The lead was discarded and has never been recovered.

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[4]Dr. Kanter does not recall having tugged on the lead.

Dr. Elias then decided to insert a surgical lead in place of the damaged percutaneous lead. This, of course, required him to perform a laminectomy. The laminectomy and implantation of the surgical lead proceeded with difficulty because of the build up of fibrosis at the place of the original electrode.

At the surgery's conclusion, Dr. Elias believed that the procedure had gone well. However, when the Plaintiff regained consciousness it became clear that this was not the case, as she complained of severe pain and immobility in her extremities. Dr. Elias suspected that the Plaintiff had suffered a spinal cord injury, which a subsequent MRI confirmed. Fisher testified that he learned that the Plaintiff had experienced complications twenty to thirty minutes after the procedure when he overheard an anesthesiologist tell Dr. Elias that the Plaintiff had no feeling in her lower extremities. Fisher claims that he did not thereafter discuss this matter directly with Dr. Elias. Thompson is less clear about how long after the procedure he learned of the Plaintiff's complications. Nonetheless, he testified that between the Plaintiff's procedure and the next one, Dr. Elias informed him that she was experiencing "some problems." Thompson did not ask Dr. Elias what these problems were, nor did Dr. Elias relay what he thought had caused them. Neither Fisher nor Thompson ever requested that the Hospital retrieve or preserve the damaged lead. Nor did they warn the Plaintiff that the lead had been discarded and that she should request its retrieval.

The Plaintiff's Contentions

The Plaintiff does not allege that the damaged lead caused her injuries in an immediate sense. Rather, she contends that a defect in the percutaneous lead caused the damage discovered during the surgery, necessitating its removal. As a result, the Plaintiff maintains, it was

medically necessary to perform a laminectomy and implant a surgical lead in place of the percutaneous lead. The Plaintiff further argues that this phase of the operation resulted in her sustaining severe injury. To this end, she offers the testimony of Dr. Elias and Dr. Urquia. In his deposition, Dr. Elias testified that he believed that the insertion of the surgical lead caused a contusion to the Plaintiff's spinal cord, resulting in the injuries sustained. Dr. Urquia was unable to pin down during deposition the cause of the Plaintiff's injury, although in a subsequently submitted affidavit he stated that he believed that the spinal cord injury occurred either during the percutaneous lead explantation, cervical laminectomy, or surgical lead implantation procedures.

The Plaintiff pursues two avenues in establishing the defectiveness of the percutaneous lead. First, she offers the testimony of Dr. Douglas Townsend, a professional engineer with a Ph.D. in metallurgy, who testified in deposition that Dr. Kanter's brief tugging on the lead ten to twelve inches from the connector could not have caused the damage observed in the lead unless it was defectively manufactured. Second, the Plaintiff argues that Fisher and Thompson's failure to act to preserve the explanted lead or to notify her of its imminent destruction constitutes spoliation of evidence, for which an adverse inference of product defect should be granted.

The Plaintiff's Experts

Dr. Douglas Townsend, Ph.D.

Dr. Townsend is a metallurgical engineer with three post-secondary degrees in metallurgy and metallurgical engineering, including a master's degree from the Massachusetts Institute of Technology and a doctorate from Queen's University. He is registered as a professional engineer in Canada and states that his areas of expertise are materials failure analysis, corrosion of metals, weld failures, thermal effects on metals and stress/impact metal failures.

Dr. Townsend has been retained as a forensic engineering expert in over 80 cases in state and federal courts in the United States. He testified in deposition that he has investigated failures involving, *inter alia*, furniture, vehicles, equipment, heating systems, cooling systems, and building systems, and also biological technologies such as mandible plates, knee joints, bone plates, and spinal plates. He has never investigated the failure of this or similar leads or any physical failure of a spinal cord stimulation system. His knowledge and experience with such systems is limited to the information obtained from reviewing the Defendant's product literature in preparation for this case. However, he did testify that he has extensive experience with urethane plastic and iridium metal, the materials out of which the lead is constructed.

Dr. Townsend intends to testify to the effect that "[t]he lead that was removed from Ms. Evans could not have been damaged according to the descriptions made by the various observers by tugging on it 10 to 12 inches from the connector unless it was defectively manufactured." Def. App., Exh. 45 at 4. In arriving at this conclusion, Dr. Townsend relied on the testimony of Dr. Elias, Fisher, and Thompson concerning Dr. Kanter's tugging on the lead, the damage observed, and the results of a tensile strength test he performed on a sample Model 3487A "PISCES-Quad" percutaneous lead on August 18, 2004.

In testing the tensile strength of the percutaneous lead, Dr. Townsend took into consideration the testimony of Dr. Elias, Fisher, and Thompson, and operated under the premise that Dr. Kanter must have been tugging on the lead some 10 to 12 inches from the connector and insulating boot and that there was a suture holding the boot in place. To replicate the pulling force caused by Dr. Kanter's tugging, Dr. Townsend used a machine to slowly apply a linear force to a sample percutaneous lead during three pull cycles over the course of about thirty

minutes.

Dr. Townsend began by screwing together the lead and connector and covering the connector with the protective boot. He then clamped the connector and lead in air jaws in a Tinius Olsen 10,000 tensile testing machine, with the jaws initially nine inches apart. During the first pull cycle, the jaws were slowly pulled apart an additional 1.7 inches over a period of fifteen minutes and exerted a maximum of 1.7 pounds of pull force on the lead. This permanently stretched the lead by about one inch. During the second pull cycle, the jaws were pulled apart to 14.2 inches, applying a maximum of 3.44 pounds of pull force. This resulted in the outer polyurethane sheath breaking and pulling back about four inches from the connector. The sheath had been stretched to 150% of its original length. The coils of the insulated wires were pulled apart. During the third cycle, three of the platinum/iridium electrical conductor lead wires suddenly broke after the lead had been pulled to a length of 23.7 inches using a maximum pull force of three pounds. These wires broke at the connector end of the lead under the insulating boot and were pulled out from underneath the boot after breaking.

From this test Dr. Townsend concluded that, based on the descriptions provided, Dr. Kanter's tugging on the lead could not have caused in the damage described unless the lead had been defectively manufactured. He claims that if Dr. Kanter had tugged on a non-defective lead hard enough to break a wire, that lead should have also been stretched from a length of about thirteen inches to a new length of about twenty-seven inches. He also concluded that it is necessary to break the sheath in half and tug it away from the connector before it is possible to tug hard enough on the sheath to break a wire in a non-defective lead.

During deposition, defense counsel questioned Dr. Townsend extensively about the

tensile strength test's sufficiency for supporting his conclusion that the damage to the lead was the result of a manufacturing defect and not some other factor. Dr. Townsend explained that he only tested the lead's tensile strength because the medical records and deposition testimony of Dr. Elias, Fisher, and Thompson did not indicate that any unusual force other than tugging was applied to the lead between its implantation and explantation. When the tensile strength test produced damage different than the damage observed in the explanted lead, Dr. Townsend concluded that Dr. Kanter's tugging could not have caused the breakage on a non-defective lead. Then, having ruled out the tugging as a cause, Dr. Townsend concluded by process of elimination that the damage must have been defectively manufactured because there was nothing else in the medical record, aside from the tugging, that indicated to him any other forces which could have caused the damage.

Defense counsel spent considerable time questioning Dr. Townsend about whether other forces, unreported in the medical notes, could have damaged the lead between its original implantation on August 20, 2003 and explantation on November 12, 2003. Dr. Townsend testified that, due to the fact that he was not able to examine the explanted lead, he could not rule out the possibility that the lead experienced compression forces, fatigue, torque, or a combination of forces during this period of time or that such forces caused the damage reported during the November 12, 2003 surgery. (Townsend dep. at 103). Dr. Townsend did offer that he could not conceive of what forces could have damaged the lead while it was implanted, but he also admitted that he was not qualified to testify about the forces to which an implanted lead might be subject. (Townsend dep. at 99, 251). Dr. Townsend also admitted that the lead could have been subjected to non-linear forces during the November 12, 2003 surgery. For example, he

acknowledged that if Dr. Kanter tugged on the lead with a pair of forceps in the direction of the Plaintiff's head, as Thompson had recalled, the lead could have become crimped or compressed at the point of contact with the forceps. Dr. Townsend further admitted that if the lead was twisted while tugging with forceps, it could have been subjected to a torsion force, a compression force and a tensile force at a given point on the lead. (Townsend dep. at 175). However, he conceded that he did not duplicate any of those forces in his test because he only had one lead and did not have more time.

Defense counsel also questioned Dr. Townsend about how accurately his tensile strength test duplicated the force with which Dr. Kanter tugged on the lead. Dr. Townsend testified that even though his test consisted of a slow, continuous pull over the course of about half an hour, it would result in the same mode of failure as a repetitive jerking or tugging force. However, the following colloquy occurred later on between defense counsel and Dr. Townsend:

> Q: So assuming no defect you employ a jerking force – your would get a different result than employing the controlled tensile force that you employed?
>
> A: No. Basically, you don't know what result you're going to get on a jerking force.
>
> Q: Until you test it?
>
> A: Well, the only way to – if you want to test the jerking force, get Dr. Canter (sic) to start jerking on various leads and see what his results are. You know, the only person that can replicate the jerking that – that Dr. Canter was exerting is Dr. Canter.
>
> Q: And, therefore, you did not replicate the jerking force Dr. Canter applied, to state the obvious?
>
> A: No.

(Townsend dep. at 115-116). Dr. Townsend also testified that a strong man can pull about one hundred pounds with both hands, or fifty pounds with one. The tensile strength test imposed a maximum force of 3.44 pounds, although Dr. Townsend did not believe that Dr. Kanter even pulled that hard because of the damage observed on November 12 was less severe than the damage caused by Dr. Townsend's test.

Finally, after Dr. Townsend concluded by process of elimination that the damage to the lead must have been caused by manufacturing defect, defense counsel questioned him about the nature of this alleged defect. Dr. Townsend testified that, due to not being able to examine the explanted lead, he did not know when the damage occurred or what caused it. Nor could he envision anything in the manufacturing process that would have caused the damage because he had not been able to examine the manufacturing process. (Townsend dep. at 252).

Dr. David C. Urquia, M.D.

Dr. David C. Urquia, M.D., is a 1983 graduate of the University of Virginia Medical School who did his internship and residency in general and thoracic surgery at Duke University. He is board certified in orthopedic surgery and is licensed to practice in North Carolina and Virginia. He practices medicine at the West End Orthopedic Clinic in Richmond, Virginia and teaches classes in orthopedic surgery at the Medical College of Virginia. He has been retained as an expert witness in at least 114 cases since 2000.

Dr. Urquia testified that the only formal exposure he has had to a spinal cord stimulation system was at a medical conference in the late 1990s in which a physician gave a presentation of implantable neurostimulators. He has never implanted a neurostimulation system such as the Medtronic Itrel 3, nor has he specifically consulted any patient about the implantation of such a

system. Dr. Urquia conceded that he does not know whether a laminectomy procedure is required to implant a percutaneous lead or a surgical lead in the cervical area of the spine. By the same token, he also stated that, prior to reviewing the Defendant's product literature, he possessed some basic knowledge of the trial and permanent implantation procedures for spinal cord stimulation systems.

The Plaintiff offers Dr. Urquia's testimony and late-submitted affidavit to establish that (1) the November 12, 2003 surgery was the direct cause of the Plaintiff's spinal cord injury, and (2) that there was reasonable medical necessity to perform the surgical lead implantation.

II. Standard of Review

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56©. Issues of material fact are genuine only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A mere scintilla of proof, however, will not prevent entry of summary judgment. *Id.* at 251. The court's function is "not . . . to weigh the evidence and determine the truth of the matter . . . [but to] determin[e] whether there is a need for a trial." *Id.* at 249-50. On a motion for summary judgment the court must view all inferences drawn from the underlying facts "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

III. Discussion

The Plaintiff seeks to recover under two theories of products liability: negligent

manufacturing and breach of implied warranty of merchantability. Both of these approaches require the plaintiff to show that (1) the device was unreasonably dangerous, and (2) the unreasonably dangerous condition existed when the device left the Defendant's hands. *See Logan v. Montgomery Ward & Co.*, 216 Va. 425, 428 (1975). A claim of negligent manufacturing also requires the Plaintiff to show that the product defect resulted from the Defendant's failure to exercise "due care" in the manufacturing process. *Chestnut v. Ford Motor Co.*, 445 F.2d 967, 969 (4th Cir. 1971). With respect to the issue of the lead being dangerously defective, the Court is presented with two issues: (1) whether Dr. Townsend's opinion is admissible to prove that the damaged lead was unreasonably dangerous when it left the Defendant's hands; and (2) if this evidence is excluded, whether the Plaintiff is entitled to a spoliation inference of product defect due to the Defendant's failure to preserve the damaged lead as evidence in potential litigation. The Magistrate's Report and Recommendation recommends that the Court not admit Dr. Townsend's opinion on the issue of product defect, but grant the Plaintiff a spoliation inference of product defect. The Plaintiff objects as to the former finding, and the Defendant as to the latter.

A. Motion to Exclude Testimony of Dr. Townsend

The Defendant offers three bases for which the Court should exclude Dr. Townsend's testimony. First, the Defendant contends that Dr. Townsend is not qualified under Fed. R. Evid. 702 to testify about the failure of the lead since he is not a doctor or biomedical engineer and lacks independent experience with spinal cord stimulation systems. Second, the Defendant argues that Dr. Townsend's testimony should be excluded because his tensile strength test was not substantially similar to the conditions of the November 12, 2003 surgery. Third, the

Defendant contends that Dr. Townsend's methodology and resulting opinion are unreliable under the standard set forth in *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993) and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), because Dr. Townsend (a) conducted the single pull tensile test without a written protocol, (b) based his test conditions on imprecise deposition testimony about Dr. Kanter's tugging, and © did not attempt to reproduce the test to assure the propriety of his results.

In his Report and Recommendation, the Magistrate found that Dr. Townsend was qualified under Rule 702 and that his reasoning and methodology passed muster under *Daubert*. However, the Magistrate ultimately recommended that the Court exclude his testimony on the basis of a lack of substantial similarity between the tensile strength test and the actual conditions during surgery. The Plaintiff filed objections as to this recommendation. Therefore, the Court will review this issue *de novo*.

Fed. R. Evid. 104(a) establishes that courts have the power to determine "preliminary questions concerning the qualification of a person to be a witness ... or the admissibility of evidence." With regard to the admissibility of expert testimony, Rule 702 provides:

> "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

The United States Supreme Court held in *Daubert*, that Rule 702 requires courts to ensure that

any and all scientific testimony or evidence admitted is not only relevant, but reliable. *Daubert*, 509 U.S. at 589. Conjecture or subjective belief or unsupported speculation will not suffice. *See id.* at 590. In performing this gatekeeping function, courts must make a preliminary determination of whether the reasoning or methodology underlying the testimony is reliable and whether that reasoning or methodology properly can be applied to the facts in issue. *Id.* at 592. The Court recognized that many factors will bear upon this inquiry and that there is no exhaustive or dispositive list of factors to be considered. *Id.* When the expert's testimony relates to causation, as Dr. Townsend's testimony does with respect to the cause of the damage to the lead, courts have often held that the failure of the expert to address alternative causes constitutes an adequate ground on which to exclude the expert testimony. *See, e.g., Aldridge v. Goodyear Tire & Rubber Co.*, 34 F. Supp. 2d 1010 (D. Md. 1999) *rev'd on other grounds,* 223 F.3d 263 (4th Cir. 2000); *Roche v. Lincoln Prop. Co.*, 278 F. Supp. 2d 744, 761-763 (E.D. Va. 2003), *rev'd on other grounds*, 373 F.3d 610 (4th Cir. 2004); *Claar v. Burlington N. R.R.*, 29 F.3d 499 (9th Cir. 1994). Courts have also excluded expert testimony when the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion. *See, e.g., General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); and *Schmaltz v. Norfolk & Western Ry. Co.*, 878 F. Supp. 1119, 1122 (N.D. Ill. 1995). The Defendant cites to Virginia law, which will exclude an expert's test if it was not performed under conditions "substantially similar to essential particulars to those existing at the time of the accident." *Featherall v. Firestone Tire & Rubber Co.*, 219 Va. 949, 959 (1979). Although the Court is not bound by this standard in making a determination of admissibility under the Federal Rules of Evidence, it does recognize the standard's usefulness as a means of gauging a test's reliability and relevance, particularly with respect to whether it rules

out alternative causes for an accident.

The Court concludes that, applying the aforementioned principles, Dr. Townsend's expert testimony is unreliable and must be excluded.[5] While the Court does not doubt that Dr. Townsend's test has some scientific merit in testing the lead's tensile strength, since the machine he used is designed to test tensile strength, it finds that his test and reasoning are not based on a reliable methodology for concluding that the lead was defectively manufactured. Nor does Dr. Townsend's test apply to the facts of this case, as it fails to meaningfully approximate the conditions during the November 12, 2003 surgery and does not exclude other reasonably conceivable explanations for damage to the lead.

The Court first considers the validity of Dr. Townsend's theory and methodology, and is careful to keep in mind the fact that the Court's scrutiny must be confined to his reasoning and methods and not his ultimate conclusions. *See Daubert,* 509 U.S. at 595. To recap, Dr. Townsend arrived at his conclusion that the explanted lead was defectively manufactured by process of elimination, which he described in the following colloquy with defense counsel:

> Q: Sir, please summarize for me what are the reasons stated in your report as required that support your opinion that damage was caused to the lead by a manufacturing defect.
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> A: I did testing, which replicated the description of the tugging, as I understand it. The

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[5]As an initial matter, the Court finds that Dr. Townsend is qualified to offer an expert opinion on the cause of the damage to the percutaneous lead. Although Dr. Townsend is not a biomedical engineer and has never investigated the physical failure of an implantable spinal cord stimulation system, he is a professional forensic engineer with a PhD in metallurgy and extensive practical experience in investigating failures of engineering systems. Moreover, he is familiar with the components of the spinal cord stimulator as a matter of general knowledge and by review of the Defendant's product literature. Thus, the Court finds that Dr. Townsend possesses the "knowledge, skill, experience, training, or education" to qualify as an expert in forensic engineering. *See* Fed. R. Evid. 702.

damage was very different from reported (sic) by the doctor; therefore, it's my opinion that it wasn't done by tugging.

There's no indication of any other damage occurring. It's not in the record, it's not in the medical notes, which leaves me with manufacturing defect.

(Townsend dep. at 248-249). Although this inductive reasoning is quite easy to follow, its problem is that it is overly simplistic and built upon conjecture and speculation. The first premise in Dr. Townsend's reasoning is that the lead had not been subjected to any damaging forces during prior procedures or while implanted in the Plaintiff, which he assumes because the medical record did not indicate to him any such forces. Yet this assumption is unreasonable because Dr. Townsend himself testified that he could not say whether the lead experienced compression or torque forces or fatigue during the various procedures prior to explantation or while in the Plaintiff's body. (Townsend dep. at 97-99). He claimed that he could not rule out these possibilities because he is not a biomedical engineer and because he did not have an opportunity to examine the lead. (Townsend dep. at 98-99). Having admitted to lacking both expertise in this respect and first hand knowledge of the damaged lead, Dr. Townsend is unjustified in concluding that the lead was not subject to damaging stresses prior to the November 12, 2003 surgery simply because the medical record did not indicate to him the presence of any such stresses. Absence of evidence is not evidence of absence.

The Court finds this speculative inference to be especially unjustified in light of the delicate nature of the lead. The Defendant's Lead Technical Manual, for example, warns about risks of lead fractures and cautions doctors that leads "may easily be damaged by improper handling or use." (Lead Technical Manual at 6, 28). Similarly, the Patient Guidelines warn that

wire breakage may occur in the lead and that "[i]t is critical to instruct patients to AVOID bending, twisting, stretching or lifting objects over five pounds, for six to eight weeks following implantation." Dr. Elias characterized the device as delicate and Dr. Hamill-Ruth testified that she has her patients wear cervical collars as a reminder to not bend, twist, or lift heavy objects since these activities can move the lead out of place or damage it. (Elias dep. at 147; Hamill-Ruth Dep. at 30). Also, Fisher has testified that he has seen perhaps a dozen fractures in similar deep brain stimulation leads due to twisting or falling. Clearly, the lead is delicate enough to be damaged while implanted and Dr. Townsend cannot simply assume, especially without expertise as a biomedical engineer or surgeon, that the lead experienced no trauma prior to explantation that could have weakened or damaged it.

The second component of Dr. Townsend's reasoning - that the lead must have been defectively manufactured - is equally speculative. Townsend, for instance, admitted that he could not explain how the lead was defectively manufactured since he had not witnessed the Defendant's manufacturing process and had not examined the damaged lead. Yet he nonetheless concluded that the lead was defectively manufactured because his test "ruled out" the possibility that the lead had been damaged by Dr. Kanter's tugging and because the medical record indicated no other forces that could have damaged the lead. What Dr. Townsend fails to explain is why a manufacturing defect is more likely the cause than some unreported damage occurring between August 20 and November 12, 2003. Given that he testified to having no direct knowledge of either possible source of harm, his conclusion that a manufacturing defect was the cause is arbitrary. It seems that he could have just as easily started his analysis at the other end, concluding that the lead had been damaged between August 20 and November 12, 2003 since he

had no evidence of any manufacturing defect. Such reasoning, which does nothing to show that a manufacturing defect was a more likely source for the damage than other possible causes, is clearly insufficient to support the Plaintiff's case. *See, e.g.,*, *Cape Charles Flying Serv., Inc. v. Nottingham* , 187 Va. 444, 451 (1948) (holding that a plaintiff's claim must "fail if it appears from the evidence just as probable that damages were caused by [one possible cause] as by the other because the plaintiff must make out his case by a preponderance of the evidence.").

The Court also finds that Dr. Townsend's test fails as to the second prong of the Court's inquiry - the applicability of his test and methodology to the facts of the case - because it did not adequately replicate many of the forces present during the November 12, 2003 surgery and, therefore, does not rule out other reasonably conceivable explanations for the damage. Again, the Court does not doubt that Dr. Townsend's test has some merit as a test of the lead's tensile strength. Its problem is that it *only* tested tensile strength using a straight linear force and ignored other possible forces suggested by the evidence. The possibility of the lead bending and experiencing a compression force during the November 12, 2003 surgery is supported by Thompson's testimony that Dr. Kanter had tugged on the lead from the flank incision and towards the Plaintiff's head with forceps and that the damage appeared in the area where the tugging occurred. In fact, Dr. Townsend admitted that this could exert a crimping or bending force on the lead, yet he did not test for the effects that these forces would have on a lead when applied simultaneously with a tensile force.

His test also fails to recreate the force exerted by Dr. Kanter's tugging. Although Fisher testified in deposition that Dr. Kanter tugged on the lead in repetitive fashion for approximately ten to fifteen seconds, Dr. Townsend's test applied a constant tensile force which slowly

increased over half an hour. His testimony as to whether these differences could bring about different results is contradictory, as in one instance he claimed that they would lead to the same result while in another instance claiming that "you don't know what result you're going to get on a jerking force." (Townsend dep. at 115-116). Also problematic is the amount of force applied by Dr. Townsend's test. His test applied a maximum force of 3.44 pounds to the lead, yet he also admitted that a "strong man" can pull with fifty pounds of force with one hand. Still, Dr. Townsend surmised that Dr. Kanter did tugged with less than 3.44 pounds of force because the amount of damage observed in the explanted lead was less than that observed in Dr. Townsend's test.[6] Assuming that Dr. Kanter never tugged the lead with up to 3.44 pounds of force, Dr. Townsend concluded that this tugging could not have broken the lead without it being defectively manufactured. This conclusion, however, is unconvincing since Dr. Townsend's lead broke under entirely different conditions. His sample lead broke when 3.44 pounds of force were being applied, but only after being slowly stretched from nine inches to nearly twenty-four. Because there is no evidence that the explanted lead had been stretched in such a fashion, the lead that Dr. Kanter tugged on would have been in a materially different condition than the one that finally broke under Dr. Townsend's test. The results observed in Dr. Townsend's test are therefore of greatly diminished value in assessing the effects that Dr. Kanter's tugging might have had on the lead. For example, his test cannot rule out the possibility that Dr. Kanter tugged with a greater amount of force, on a lead that had not been stretched by nearly 14 inches, and that this resulted in a different degree of damage to the lead wires. The Court thus finds that Dr. Townsend's test

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[6]Three wires were broken in Dr. Townsend's test, compared to one broken wire observed during surgery.

does not adequately resemble Dr. Kanter's repetitive tugging and, therefore, does not exclude this tugging as a possible cause of the damage to the lead.

In sum, the Court is sympathetic to the difficulties that plaintiffs might have in recreating the forces that a lead might experience while being manipulated during surgery or while implanted in the human body. The law, as a consequence, does not require experimental exactitude. Yet the Court finds that in this case Dr. Townsend's single tensile strength test did not adequately account for compression, bending, and tugging forces suggested by the evidence. Similarly, the Court finds his overall reasoning, which assumes the absence of any damaging forces unreported in the medical record in order to arrive at the conclusion of defective manufacturing, to be faulty and speculative. Thus, the Court will grant the Defendant's motion to exclude Dr. Townsend's expert testimony.

B. Plaintiff's Motion for a Spoliation Inference

Dr. Townsend's testimony as to product defect having been excluded, the Court will now examine the possibility that the Plaintiff could establish an inference of product defect through a spoliation of evidence inference. In her memorandum in opposition to the Defendant's Motion for Summary Judgment, the Plaintiff argues that Fisher and Thompson spoliated evidence by failing to preserve the explanted lead in anticipation of litigation, entitling her to an inference that the lead was defectively manufactured. The Magistrate agreed in his Report and Recommendation and granted an inference of product defect. The Defendant filed timely objections to this recommendation, which the Court reviews *de novo*.

Spoliation of evidence is "the destruction or material altercation of evidence or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable

litigation." *Silvestri v. General Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001). In pre-litigation situations, the duty to preserve material evidence exists where "a party reasonably should know that the evidence may be relevant to anticipated litigation." *Id.* at 591 (citing *Kronisch v. United States*, 150 F.3d 112, 126 (2nd Cir. 1998)). "If a party cannot fulfill this duty to preserve because he does not own or control the evidence, he still has an obligation to give the opposing party notice of access to the evidence or of the possible destruction of the evidence if the party anticipates litigation involving that evidence." *Id.*

Federal courts have the right to impose sanctions for spoliation as a part of their inherent power to control the judicial process. *Id.* at 590. The sanction imposed by the court "should be molded to serve the prophylactic, punitive, and remedial rationales underlying the spoliation doctrine." *Id.* (quoting *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2nd Cir. 1999). One possible sanction is a "spoliation inference," which is an inference that the evidence no longer available would have been adverse to the party that made it unavailable. *Bolling v. Montgomery Ward & Co., Inc.*, 930 F. Supp. 234, 237 (W.D.Va. 1996). This inference stems from the common sense observation that when a party destroys evidence that he knows is likely to be relevant to future litigation, it is likely that the party believed such evidence to be adverse to his interests. *See Anderson v. National R.R. Passenger Corp.*, 866 F. Supp. 937, 945 (E.D. Va. 1994) (citing *Nation-wide Check Corp. v. Forest Hills Distributors, Inc.*, 692 F.2d 214, 218 (1st Cir. 1982)). Given this rationale for the spoliation inference, courts must find some degree of fault or blameworthiness to impose sanctions. *Id.*; *Silvestri*, 271 F.3d at 590. An adverse inference "cannot be drawn merely from [a party's] negligent loss or destruction of evidence; the inference requires a showing that the party knew the evidence was relevant to some issue at trial

and that his willful conduct resulted in its loss or destruction." *Hodge v. Wal-mart Stores, Inc.*, 360 F.3d 446, 450 (4th Cir. 2004) (quoting *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995)). Although a spoliation inference does not necessarily require that the spoliator acted in bad faith, *Vodusek*, 71 F.3d at 156, the doctrine of spoliation is nonetheless concerned with misbehavior by parties. *See, e.g., Bolling*, 930 F.Supp. at 238 ("[T]he spoliation doctrine applies only to misbehavior by parties."); and *Hodge*, 360 F.3d at 451 (declining to find spoliation in part because of a lack of evidence that the alleged spoliator abused the judicial process in failing to obtain the contact information of a witness to the accident at the center of the case).

In order for an adverse spoliation inference to be appropriate in this case, the Plaintiff must show that (1) the Defendant's representatives should have anticipated litigation surrounding the damaged lead, giving rise to a duty to preserve the evidence or notify the Plaintiff of its destruction; and (2) their willful conduct resulted in the destruction of the evidence. The Plaintiff advances several arguments in favor of granting a spoliation inference. First, she claims that the Fisher and Thompson were put on notice of future litigation surrounding the lead because they knew that the Dr. Elias had unexpectedly found the lead to be damaged during the surgery, necessitating an invasive laminectomy, and that she reported severe complications soon after surgery. She also points out that Fisher learned of these complications within twenty to thirty minutes of the surgery's completion. Second, the Plaintiff claims that Fisher and Thompson had a duty to attempt to retrieve the lead because of a United States Food & Drug Administration regulation, which requires medical device manufacturers to report to the FDA a device-related death, injury, or malfunction within thirty days after becoming aware of the event, and to

investigate the cause thereof. 21 C.F.R. 803.50. The Plaintiff does not cite any authority for the proposition that any breach of this duty to report would warrant the imposition of a spoliation inference, but argues that the FDA regulation is designed to protect third parties, such as herself, who use medical devices.

The Defendant objects to the Magistrate's finding that Fisher and Thompson spoliated evidence and to his recommendation that the Court grant an inference that the lead was defectively manufactured. The Defendant contends that neither Fisher nor Thompson could have anticipated litigation surrounding the damaged lead, pointing to their testimony that they attributed the damage to Dr. Kanter's tugging, not to product defect, and that they did not attribute the Plaintiff's complications to the damaged lead when they learned of them. The Defendant also argues that there is no evidence that Fisher and Thompson willfully caused the destruction of evidence because they never attributed the Plaintiff's injuries to the lead and because they never came into possession of the lead before its disposal. Finally, the Defendant argues that the facts of this case are analogous to cases in the Fourth Circuit where courts have found no spoliation of inference.

Having thoroughly considered the contentions of each party, the Court agrees with the Defendant and finds that the facts of this case do not warrant a finding of spoliation or an imposition of an inference of product defect. First, the Court finds that Fisher and Thompson reasonably did not anticipate future litigation surrounding the damaged lead. While the reports of Plaintiff's complications should have made the prospect of some kind of litigation a reasonable possibility, it was less obvious that this potential litigation would involve a products liability claim involving the damaged lead. The testimony of Dr. Elias, Fisher, and Thompson

does not indicate that the possibility of a product defect was on anyone's minds during the surgery or its immediate aftermath. Fisher, for example, testified at deposition that he does not recall there being any discussion during the surgery about the damaged lead being a result of a defect. Instead, Fisher recalled that Dr. Kanter's tugging on the lead prompted him to make a comment to Thompson about the dangers that this posed to the integrity of the lead.[7] Nor does Thompson's testimony give any indication that either he, Fisher, or Dr. Elias attributed the damage to a product defect. Similarly, Dr. Elias did not attribute the lead's damage to defective manufacturing either on the date of the surgery or during his later deposition. In fact, at deposition he testified that he had not thought about retrieving the damaged lead for warranty purposes, even though he knew that this would require the lead to be sent to the manufacturer.

Nor do the circumstances of the surgery and its immediate aftermath suggest that Fisher or Thompson reasonably should have anticipated litigation to the point of obligating them to preserve the lead. Certainly, they could not have anticipated litigation during the course of surgery because no one knew at that point that the Plaintiff had been or would be injured. Even after Fisher and Thompson learned of the Plaintiff's complications it could not have been clear that litigation surrounding the lead would ensue. Although the lead had been damaged, the record does not indicate that anyone related this to a product defect. Also, it was reasonable for Fisher and Thompson to not connect the damaged lead to the Plaintiff's injuries because they had not learned of the full extent of her injuries and because the Plaintiff had also undergone an invasive laminectomy and an implantation of a surgical lead, which proceeded with difficulty due

[7]Fisher added during his deposition that of the dozen or so fractures that he has seen in deep brain stimulation leads, he has not attributed any to product defect rather than external stimuli.

to the buildup of scar tissue.

The Court also notes that, compared to other Fourth Circuit cases in which a spoliation inference was upheld, this case contains a weaker basis for finding that litigation should have been anticipated. In *Silvestri*, for example, the spoliation of evidence involved a plaintiff who was injured in a car accident when his car's airbags failed to deploy. 271 F.3d 583. Despite the fact that the car remained in its damaged condition for three months, during which time the plaintiff retained an attorney and had experts examine the car, the plaintiff did not notify the defendant of the accident until three years after the accident, when the car had already been repaired and sold. *Id.* at 586-87. Similarly, *Vodusek* involved destruction of evidence after the plaintiff had anticipated litigation and taken steps in preparation of it. In that case, the plaintiff's husband died of injuries sustained when his boat exploded. Several months later after the accident, when the plaintiff had already decided to sue the boat's manufacturer on products liability grounds, the plaintiff's counsel employed an expert witness to inspect the boat for defect, resulting in considerable damage to the portions of the boat relevant to the alleged defect. *Vodusek v. Bayliner Marine*, 1994 A.M.C. 2343, 2345 (D. Md. 1994). Under such conditions, the Fourth Circuit upheld the lower court's decision to submit the question of spoliation to the jury. The circumstances in the instant case, by contrast, present a much weaker case for imposing a spoliation inference. Unlike the plaintiffs in *Silvestri* and *Vodusek*, both of whom actually suspected that their boat or vehicle was defective and connected this defect to the respective accidents, Fisher and Thompson do not appear to have suspected any defect or to have connected the lead with the Plaintiff's injuries. Nor does the record indicate that they took any steps in anticipation of litigation which could suggest that they did suspect a defect.

The Court also agrees with the Defendant that Fisher and Thompson did not wilfully contribute to the lead's destruction. The record makes clear that Fisher and Thompson never possessed the explanted lead and that the scrub nurse was the last known person to possess it and was, presumably, the one who disposed of it. Not only did Fisher and Thompson not actually destroy the lead, the circumstances of the day do not suggest that they had they duty to take steps to preserve it. First, for the reasons discussed *supra*, they reasonably did not anticipate that the lead would be relevant to future litigation. Second, aside from the issue of what they believed about the lead, they were not charged with the responsibility of acquiring the lead for any other purpose. For example, Fisher and Thompson had no duty to preserve the damaged lead for warranty purposes because it was the hospital's duty to retrieve it and send it to the Defendant for such purposes. Also, the Court does not find the Plaintiff's argument that the Defendant's FDA reporting requirement can serve as a premise for imposing an inference adverse to the Defendant. The Plaintiff cites no persuasive or controlling authority for this proposition, nor has the Court's research uncovered any such authority. Third, the Court finds the time-frame of the day's events to mitigate against a finding of willful destruction of evidence. Unlike the plaintiffs in *Silvestri* and *Vodusek*, who possessed the evidence for days or weeks before causing its destruction or loss, Fisher and Thompson only had potential access to the lead for a brief period of time and under the more hurried setting of a hospital.[8]

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[8] The facts relating to Fisher and Thompson's access to the evidence more closely resembles *Hodge*, than *Silvestri* or *Vodusek*. In *Hodge*, the Fourth Circuit upheld the district court's decision to not grant a spoliation inference in a case involving a customer who was injured when mirrors fell on her from a high shelf at one of Wal-Mart's stores. *Id.* 360 F.3d at 448. An employee of the store allowed a witness to leave without obtaining any contact information because of his belief that all of the relevant evidence would be captured on security cameras, which turned out to not be the case. *Id.* at 448-449. In holding that an inference of

In sum, the Court finds the apparent lack of willful destruction of evidence on the part of Fisher and Thompson's part to be important in denying the Plaintiff's motion for a spoliation inference. The rationale for imposing an adverse inference against a spoliator is that the spoliation of evidence indicates consciousness that the evidence in question is adverse to the spoliator's interests. *See Anderson*, 866 F. Supp. at 945. The evidence before the court - including evidence that Fisher and Thompson did not have a duty to retrieve the lead and did not associate the Plaintiff's complications with the damaged lead - does not indicate that they failed to take steps to preserve the lead or notify the Plaintiff of its possible destruction out of any desire to cause the loss of this evidence. In hindsight, it would have been prudent for them to retrieve the lead or notify the Plaintiff of its disposal, but their failure to do this at most would fall more along the lines of negligence than willful conduct.

Therefore, the Court will not impose a spoliation inference of product defect.

C. The Plaintiff's Claims for Negligent Manufacturing and Breach of Warranty

In order to recover under claims for either negligent manufacturing or breach of warranty, the Plaintiff must show that (1) the device was unreasonably dangerous, and (2) the unreasonably dangerous condition existed when the device left the Defendant's hands. *Logan*, 216 Va. at 428. A claim of negligent manufacturing also requires the Plaintiff to show that the product defect

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spoliation was not warranted, the court noted that Wal-Mart did not willfully fail to preserve evidence because there was no evidence that the store employee intentionally deceived the accident victim or the witness about the security camera's capabilities in explaining why the witness did not need to stay. *Id.* at 451. The court also found that the circumstances surrounding the accident were not the proper context for giving rise to an inference of spoliation because the store employee only had access to the witness under "hurried conditions" for a brief period of time. *Id.*

resulted from the Defendant's failure to exercise "due care" in the manufacturing process. *Chestnut*, 445 F.2d at 969.

Under Virginia law, a defendant is entitled to summary judgment if there are two or more potential causes for the plaintiff's injuries and the plaintiff cannot show that the defendant's acts caused the injuries. *Boyle v. United Techs. Corp.*, 792 F.2d 413, 415 (4th Cir. 1986); *Cape Charles Flying Service, Inc.*, 187 Va. at 451. In a case involving injuries arising out of an allegedly defective product which can no longer be produced, this requires the plaintiff to negate all reasonable alternative explanations for the product's malfunctioning. *See Logan*, 216 Va. at 429; *Lemons v. Ryder Truck Rental*, 906 F. Supp. 328, 332 (W.D. Va. 1995). This burden remains even where the product is unavailable through no fault of the plaintiff. *Bolling v. Montgomery Ward & Co.*, 930 F. Supp. at 238. A mere suspicion that the malfunctioning is the result of a defect, absent actual proof of a defect, is not enough for the plaintiff to survive a motion for summary judgment. *Id.*

Dr. Townsend's testimony having been excluded and no spoliation inference of product defect having been imposed, it is clear that the Plaintiff's claims for breach of warranty and negligent manufacturing must fail due to a lack of evidence that the Defendant's lead was defective. Indeed, without Dr. Townsend's testimony and the spoliation inference, the Plaintiff has no evidence whatsoever that the percutaneous lead was defective.[9] Also lacking is sufficient evidence to negate the reasonable possibility that some other factor, whether that be Dr. Kanter's

[9]The record is similarly devoid of any evidence that the Defendant failed to exercise due care in the manufacturing process.

tugging or the stresses endured by the lead while implanted, caused the damage discovered in the lead. Undoubtedly, the Plaintiff's task in ruling out alternative explanations is much more difficult in light of the unavailability of the lead, but the Court cannot ignore the fact that the Plaintiff retains the burden of proof in this case. While one might be tempted to suspect a product defect when a split is discovered in a lead designed to withstand the hostile environment of the human body, a mere suspicion unaccompanied by evidence of a defect will not suffice. The Court, therefore, must grant the Defendant's motion for summary judgment due to the insufficiency of evidence establishing product defect and negating reasonable alternative explanations for the damage.

IV. Conclusion

For the above stated reasons, the Court will grant the Defendant's motion to exclude the testimony of Dr. Douglas Townsend and will not impose a spoliation inference of product defect. There being no other evidence that the percutaneous lead was defective, the Court will grant the Defendant's motion for summary judgment on the Plaintiff's claims of negligent manufacturing and breach of implied warranty of merchantability. Accordingly, the Magistrate's Report and Recommendation shall be rejected. Because the Plaintiff's claims will be dismissed on the issue of product defect, it is not necessary for the Court to consider motions relating to issues of causation and the medical necessity of the laminectomy. Therefore, the Court will not address the Defendant's motion to exclude the expert testimony of Dr. David Urquia or the motion to strike the late-filed affidavits of Dr. Urquia and Dr. W. Jeffery Elias.

The Clerk of the Court hereby is directed to send a certified copy of this Memorandum Opinion to all counsel of record and to Magistrate Judge Crigler.

ENTERED: Hann C Moore

United States District Judge

December 27, 2005

Date